Notice of Allowability	Application No.	Applicant(s)	
	10/706,275	LOWELL ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *4/2/07*.

2. ☒ The allowed claim(s) is/are *3, 5, 6, 8-10 and 13-19; now renumbered 1-13 respectively*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *attached* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 7, 2006 has been entered.

2. Applicants' amendment filed December 7, 2006 (and the attached Examiner's amendment) is acknowledged and has been entered. Claims 1, 2, 4, 7, 11 and 12 have been canceled. Claims 3, 5, 6, 9 and 16 have been amended. Claims 3, 5, 6, 8-10 and 13-19 are now pending in the present application. All rejections have been withdrawn in view of amendment to the claims (see below) and/or comments.

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mae Joanne Rosok, 48903 on April 2, 2007.

4. The application has been amended as follows:

1.-2. (Cancelled)

3. (Previously Presented) A vaccine composition comprising a proteosome adjuvant and a group A Streptococcal antigen that comprises an antigenic peptide between 15 and 30 amino acids in length from the conserved C-terminal region of an *S. pyogenes* M protein, wherein the antigenic peptide comprises the amino acid sequence ASREAKKQVEKALE (SEQ ID NO:1), and wherein the antigen is attached to a hydrophobic moiety.

4. (Canceled)

5. (Previously Presented) The vaccine composition according to claim 3 wherein the antigen comprises the antigenic peptide flanked by amino acid sequences to maintain helical folding of the antigen.

6. (Previously Presented) The vaccine composition according to claim 5 wherein the antigen comprises the sequence KQAEDKVKASREAKKQVEKALEQLEDKVK(SEQ ID NO:2).

7. (Cancelled)

8. (Previously Presented) The vaccine composition according to claim 3 wherein the hydrophobic moiety is attached at the N-terminal end or C-

terminal end of the antigen for complexing the antigen with the proteosome adjuvant.

9. (Previously Presented) The vaccine composition according to claim 3 wherein the composition is formulated for mucosal administration.

10. (Previously Presented) The vaccine composition according to claim 9 wherein mucosal administration is intranasal.

11. - 12. (Cancelled)

13. (Previously Presented) The vaccine composition according to claim 3 wherein administration of the composition to an individual induces a mucosal immune response.

14. (Previously Presented) The vaccine composition according to claim 3, wherein administration of the vaccine composition induces a serum immune response.

15. (Previously Presented) The vaccine composition according to claim 9 wherein the vaccine composition is capable of treating or preventing a group A Streptococcal infection via reducing or preventing streptococcal group A bacterial colonisation of the throat.

16. (Previously Presented) A method of treatment or prophylaxis of group

A Streptococcal infection in an individual comprising administering the vaccine composition according to claim 3 to the individual.

17. (Previously Presented) The method according to claim 16 wherein said vaccine composition is administered intranasally to said individual.

18. (Previously Presented) The method according to claim 17 wherein the treatment or prophylaxis of the group A Streptococcal infection is produced via prevention or reduction of bacterial colonisation of the throat.

19. (Previously Presented) The vaccine composition according to claim 3 wherein the antigen further comprises a spacer peptide comprising at least two glycine residues, and wherein the spacer peptide links the antigenic peptide and the hydrophobic moiety.

5. Claims 3, 5, 6, 8-10 and 13-19 have been allowed and renumbered 1-13 respectively.

6. The following is an examiner's statement of reasons for allowance: The closest prior art does not teach or suggest a vaccine composition comprising a proteosome adjuvant and a group A Streptococcal antigen that comprises an antigenic peptide between 15 and 30 amino acids in length from the conserved C-terminal region of an *S. pyogenes* M protein, wherein the antigenic peptide comprises the amino acid sequence ASREAKKQVEKALE (SEQ ID NO:1), and wherein the antigen is attached to a hydrophobic moiety.

The prior art (Lowell et al) teaches the exact opposite region (amino terminal portions) of the *S. pyogenes* M protein being antigenic peptide and used in the vaccine composition.

It is noted that claim 4 has been canceled solely to expedite prosecution of certain specific embodiments. Applicants have cancelled claim 4 without acquiescence to a 112, 2nd rejection and without prejudice to prosecuting the cancelled subject matter in a related divisional, continuation, or continuation-in-part application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
April 2, 2007

CLEAN COPY OF ALLOWED CLAIMS

3. A vaccine composition comprising a proteosome adjuvant and a group A Streptococcal antigen that comprises an antigenic peptide between 15 and 30 amino acids in length from the conserved C-terminal region of an *S. pyogenes* M protein, wherein the antigenic peptide comprises the amino acid sequence ASREAKKQVEKALE (SEQ ID NO:1), and wherein the antigen is attached to a hydrophobic moiety.

5. The vaccine composition according to claim 3 wherein the antigen comprises the antigenic peptide flanked by amino acid sequences to maintain helical folding of the antigen.

6. The vaccine composition according to claim 5 wherein the antigen comprises the sequence KQAEDKVKASREAKKQVEKALEQLEDKVK(SEQ ID NO:2).

8. The vaccine composition according to claim 3 wherein the hydrophobic moiety is attached at the N-terminal end or C-terminal end of the antigen for complexing the antigen with the proteosome adjuvant.

9. The vaccine composition according to claim 3 wherein the composition is formulated for mucosal administration.

10. The vaccine composition according to claim 9 wherein mucosal administration is intranasal.

13. The vaccine composition according to claim 3 wherein administration of the composition to an individual induces a mucosal immune response.

14. The vaccine composition according to claim 3, wherein administration of the vaccine composition induces a serum immune response.

15. The vaccine composition according to claim 9 wherein the vaccine composition is capable of treating or preventing a group A Streptococcal infection via reducing or preventing streptococcal group A bacterial colonisation of the throat.

16. A method of treatment or prophylaxis of group A Streptococcal infection in an individual comprising administering the vaccine composition according to claim 3 to the individual.

17. The method according to claim 16 wherein said vaccine composition is administered intranasally to said individual.

18. The method according to claim 17 wherein the treatment or prophylaxis of the group A Streptococcal infection is produced via prevention or reduction of bacterial colonisation of the throat.

19. The vaccine composition according to claim 3 wherein the antigen further comprises a spacer peptide comprising at least two glycine residues, and wherein the spacer peptide links the antigenic peptide and the hydrophobic moiety.